IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS (GLP-1 RAS) PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION**
	:	**MDL No. 3094**
	:	**24-md-3094**
THIS DOCUMENT RELATES TO:	:	
	:	**HON. KAREN SPENCER MARSTON**
	:	**Filed Conditionally Under Seal Pursuant to Order Re: Filing Documents Under Seal ECF 187-2**
ALL ACTIONS/ALL CASES	:	

PLAINTIFFS' OBJECTIONS TO SPECIAL MASTER LAWRENCE F. STENGEL'S REPORT AND RECOMMENDATION REGARDING PLAINTIFFS' REQUEST FOR PRODUCTION OF ANIMAL HISTOPATHOLOGY SLIDES

INTRODUCTION

On September 8, 2025, Special Master Hon. Lawrence F. Stengel ("the Special Master") issued a Report and Recommendation ("R&R") denying Plaintiffs' request for production of animal histopathology slides ("Slides") for a limited number of preclinical studies conducted by Defendants Eli Lilly ("Lilly") and Novo Nordisk ("Novo"). Ex. 1, September 8, 2025 R&R (Dkt. 490).

LEGAL STANDARD

Pursuant to Fed. R. Civ. P. 53(f)(2) and CMO No. 16 (Dkt. 213), "[a] party may file objections to … the master's order, report, or recommendations" within five business days of the filing of the R&R. Fed. R. Civ. P. 53(f)(3) and (4) provide that "[t]he court must decide de novo all objections" to findings of fact and conclusions of law by the Special Master.

ARGUMENT

A. Plaintiffs' Satisfied Rule 26 to Warrant Production of the Limited Requested Animal Histopathology Slides

The Special Master concluded that the slides requested by Plaintiffs are relevant[1] and that, when weighing proportionality, "there is no doubt that the first three factors [of Fed. R. Civ. P. 26(b)(1)] favor production." Ex. 1 at 7, 9. Indeed, as the Special Master acknowledged, "[i]t cannot be said that the Slides have no tendency to prove or disprove issues related to the Defendants' representations to the FDA." Ex. 1, at 7. The Special Master's R&R denying production, however, ultimately rested upon Fed. R. Civ. P. 26(b)(1) factors related to the importance of the preclinical slides to this litigation and the burden associated with their production.

[1] Once discovery has been deemed relevant, "[t]he burden then shifts to the party resisting discovery to justify withholding it." *Morrison v. Philadelphia Hous. Auth.*, 203 F.R.D. 195, 196 (E.D. Pa. 2001). The party resisting discovery is required to show disproportionate burden. *See First Niagara Risk Mgmt., Inc. v. Folino,* 317 F.R.D. 23, 28 (E.D. Pa. 2016). Defendants have not done so. Defendants' have made boilerplate objections and have not submitted any declarations, affidavits, or testimony relating to any alleged burden.

Under Rule 26(b)(1), "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case…". The advisory committee's note to the 2015 Amendment for Rule 26 makes clear that Fed. R. Civ. P. 26(b)(1)'s proportionality calculation "does not place on the party seeking discovery the burden of addressing all proportionality considerations" and that "[a] party claiming that a request is important to resolve the issues should be able to explain the ways in which the underlying information bears on the issues as that party understands them." Plaintiffs have done so here.

Plaintiffs satisfied the Rule 26 "importance" prong by explaining the ways in which the underlying slides bear on the issues in this litigation.[2] Pre-clinical studies, including animal studies, are required by FDA and conducted *specifically* to identify any possible safety signals. The intent of pre-clinical studies, in addition to carcinogenesis evaluation, is that any histopathologic or other sign of a possible issue can then be considered for further pre-approval study or for heightened vigilance in both the clinical trials and the post-marketing period.[3] This is one reason why they are important to this case. However, this evidence touches not just on notice and fully informing the FDA, but also is important for the evaluation of causation. At oral argument, Plaintiffs pointed out that the limited subset of studies sought were deemed pivotal by both Defendants and the FDA, demonstrating the significance of these studies.[4] The bottom line is that if the Plaintiffs are deprived of this evidence, the Court cannot fairly and justly evaluate and decide any of the

[2] *See* Ex. 2, Plaintiffs' Expert Kevin M. O'Brien, VMD, MVetMed, DACVP, MRCVS, expert report. Plaintiffs note that while the Special Master concluded that Dr. O'Brien failed to connect the requested pathology to Plaintiffs' claims, the Report clearly lays out the relevance of pathology in relation to the injuries at issue. *See also* Ex. 3, Plaintiffs' December 2024 Letter; and Ex. 4, Plaintiffs' August 2025 Letter.

[3] *See* 21 C.F.R. § 201.57(c)(14); 21 CFR § 312.23(a)(8); 21 CFR § 312.32(b), 21 CFR § 312.32(c)(1)(iii); and FDA, *Draft Guidance for Industry: Obesity and Overweight: Developing Drugs and Biological Products for Weight Reduction, Guidance for Industry* (January 2025), https://www.fda.gov/media/71252/download (last visited September 15, 2025).

[4] Indeed, Plaintiffs request was exceptionally narrow – [redacted]

upcoming Issue 2 and 3 Rule 702 or Rule 56 motions.

Furthermore, the R&R places a burden standard on Plaintiffs that is essentially impossible to meet without having the benefit of the discovery sought. It imposes, for example, that Plaintiffs identify a "specific instance in which the content of any animal slides was misrepresented to the FDA." Ex. 1, at 8. As stated in Plaintiffs' August 7, 2025, submission, Defendants' internal written characterizations of the slides cannot allow any expert to evaluate what Defendants missed or failed to properly interpret. Ex. 4, Plaintiffs' August 7, 2025, Letter. Experts must lay eyes on the slides to do this. The accuracy of the Defendants' *mere statements* as to the slides is *precisely* what Plaintiffs are entitled to evaluate. Moreover, Plaintiffs *have* identified instances where the content of animal studies were mischaracterized to the FDA.[5] Without the requested discovery, Plaintiffs are unable to identify with the level of specificity the Special Master requires and are therefore left with nothing other than taking Defendants' at their word.[6] Decades of experience guides Plaintiffs' hesitancy to blindly accept Defendants' representations related to preclinical evidence.

In assessing the burden or expense of the proposed discovery, the Special Master found the burden associated was great. Plaintiffs again respectfully disagree. Plaintiffs have shown both with prior MDLs (for example, *In re Proton Pump Inhibitor ("PPI") Prods. Liab. Litig.*, 2022 WL 18999830 at 42 (D.N.J. Dec. 5, 2022) where even older tissue was produced than sought here), and internal documents showing Defendants' electronic repositories and archival policies that

[5] [redacted]

[6] The Special Master's R&R related to the production of Adverse Event Source Files is instructive here. There, the Special Master noted that Source files were "not uniform document types and are not located in a single place (physical or electronic)" and spread in different repositories; yet, the Special Master recommended the raw Source File data be produced to Plaintiffs as "comparison of source files to the final AERs submitted to the FDA may inform Plaintiffs' claims". *See* Ex. 9, May 21, 2025, R&R on production of Adverse Event Source Documents at 3-4.

production would not unduly burdensome. The *potential* number of pathology slides does not automatically foreclose production.[7]

B. The Special Master's Reliance on Gardasil is Misplaced and Other MDLs Have Ordered Similar Productions.

The Special Master relies on an order in the Gardasil MDL precluding preclinical discovery. However, as Plaintiffs explained in their July 25, 2025, Letter, Gardasil is distinguishable.[8] [redacted]

The Special Master also concluded in his R&R that Plaintiffs did not cite a case where histopathology slides of this nature and with "this level of burden" were ordered for production. Ex. 1, at 8. Respectfully, that is incorrect. At oral argument on July 24, 2025, Plaintiffs pointed to four cases where a production was ordered: (1) *In re Proton Pump Inhibitor ("PPI") Prods. Liab. Litig.,* 2022 WL 18999830 at 42 (D.N.J. Dec. 5, 2022), (2) *In re Diet Drugs*, 2001 WL 454586, at 11 (E.D. Pa. Feb. 1, 2011), (3) *In Re Accutane Trial,* 2008 WL 5611668 (Superior Court of New Jersey), and (4) *In Re Roundup Products Liability Litigation*, MDL No. 2741, Case No. 16-md-02741-vc (N.D. Cal. 2017). In fact, far more slides were produced in the PPI MDL than Plaintiffs have requested here.

[7] Plaintiffs have requested information from Defendants multiple times to no avail, including how many slides are available per study, what format the pathology data exists, and how long it would take to produce the available slides. Defendants have refused to provide this information, and it is therefore impossible to know any true burden associated with Plaintiffs request, assuming one even exists.

[8] For example, the injuries alleged in the Gardasil MDL were autoimmune in nature and plaintiffs did not identify at argument on this issue whether the requested pathology would provide information about the autoimmune injuries alleged. *See* Ex. 6, Plaintiffs July 25, 2025, Letter.

C. Plaintiffs Have Not Delayed in Seeking this Discovery.

Respectfully, contrary to the findings in the R&R, Plaintiffs have not delayed the pursuit of these slides. On April 8, 2024, Plaintiffs requested "[a]ll documents reflecting or relating to any studies, clinical studies, or laboratory and/or animal testing on the safety or efficacy of any GLP-1 RAs.". Ex. 7 and 8, Plaintiffs' First Set of RFPs. On December 11, 2024, Plaintiffs wrote to the Special Master explaining the specific relevance of these slides.[9] The parties continued to meet and confer in an attempt to resolve disagreement without judicial intervention. The Defendants implied that an agreement of some kind could be reached, but we need to work out the extent and the details. On January 28, 2025, Plaintiffs sent a detailed, proposed pathology protocol to Defendants. On February 26, 2025, the Novo Defendant provided Plaintiffs with a list of preclinical studies and within weeks, Plaintiffs reviewed that information and provided Novo with a limited set of studies for production.[10] Defendants had all necessary information to begin the collection and digitization of the requested pathology slides. Throughout March, Plaintiffs parsed out the exact tissues per organ, per study as requested by Defendants. In mid-April 2025, Plaintiffs and Defendants had an extensive meet and confer, and Plaintiffs believed progress was being made. On June 30 and July 1, 2025, Plaintiffs circulated revised draft protocols. Thereafter, it became clear to Plaintiffs that additional meet and confers would not be useful and Plaintiffs revisited the issue to the Special Master on July 8, 2025, and a hearing was set. There was no delay by Plaintiffs.[11]

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[9] Plaintiffs specifically identified interstitial cells of Cajal and other pathology findings that are only seen on the slides themselves. *See* Ex. 3, Plaintiffs' December 11, 2024, Letter.

[10] Plaintiffs similarly requested a limited number of preclinical studies to the Lilly Defendant.

[11] It is worth noting that the Court indicated at the September 3, 2025, in-person status conference related to the Novo 483 Issue, "…obviously there is a deadline coming up. But at the same time, this issue [related to Novo's 483] I sort of – we know – we've all known could need extra time, right?" Counsel for Novo replied, "Exactly." *See* Ex. 5, Sept. 3, 2025 Transcript Excerpt, 97:4-7, 97:8. Thus, there was no delay here, but the 483 issue causing far greater delay instructs that delay should not bear on this issue here.

CONCLUSION

For these reasons, this Court should reject the Special Master's recommendation and grant Plaintiffs' discovery request in its entirety.

Dated: September 16, 2025

RESPECTFULLY SUBMITTED,

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CERTIFICATE OF SERVICE

I hereby certify that on September 16, 2025, a true and correct copy of the foregoing document was electronically filed using the Court's CM/ECF System, which will send notification of such filing to all counsel of record.

/s/ Paul J. Pennock
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